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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,841	08/08/2001	David R. Dilley	MSU 4.1-560	2882
21036	7590	06/02/2005	EXAMINER	
MCLEOD & MOYNE, P.C. 2190 COMMONS PARKWAY OKEMOS, MI 48864			PAK, YONG D	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,841

Applicant(s)

DILLEY ET AL.

Examiner

Yong D. Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,11,12 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-3, 11-12 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a divisional of 09/413,231, now issued as U.S. Patent No. 6,284,483.

The amendment filed on March 14, 2005, canceling claims 1, 4-10, 13-16 and 18-50 and amending claims 2-3, 11-12 and 17, has been entered.

Claims 2-3, 11-12 and 17 are pending and are under consideration.

Claim Objections

Claim 3 is objected to because of the following informalities: the claim recites the term "organism". It appears that applicants have meant to recite "microorganism" since claim 2 recites a microorganism and not an organism. Appropriate correction is required.

Claim 11 is objected to because of the following informalities: the claim recites the phrase "DNA comprises an IPNS like SEQ ID NO:1". It appears that applicants have meant to recite "DNA encodes an IPNS like SEQ ID NO:1" since SEQ ID NO:1 is an amino acid sequence not a nucleic acid sequence.

Response to Arguments

Applicant's amendment and arguments filed on March 14, 2005, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 depend from claims, which have been canceled, and therefore the limitations of said claims are highly unclear. Therefore, the claim has not been considered under other statutes.

Claims 2 and 11 and claims 3 and 12 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 11 recite the phrase "IPNS like SEQ ID NO:1". The metes and bounds of this phrase are not clear to the Examiner. It is not clear to the Examiner either from the specification or from the claims as to what applicants mean by the above phrase. It is not clear to the Examiner if the IPNS like protein has all the properties of IPNS or only some properties of IPNS. It is also not clear to the Examiner whether the IPNS "like SEQ ID NO:1" encompasses a single specific enzyme (SEQ ID NO:1) or whether it encompasses recombinants, variants and mutants of the IPNS of SEQ ID NO:1. As applicants have not provided a definition for the above phrase, Examiner has

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interpreted the claims broadly to mean that an IPNS "like SEQ ID NO:1" encompasses polypeptides which are recombinants, variants or mutants of SEQ ID NO:1 having a Arg at position 212. Examiner has given the same interpretation while considering the claims for all other rejections. The rejection can be overcome by amending the phrase to recite "IPNS having the amino acid sequence of SEQ ID NO:1".

Claim 11 and claim 12 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the phrase "codon 214His Arg". It is not clear to the Examiner either from the specification or from the claims as to what applicants mean by the above phrase. The phrase is not clear to the Examiner because the term "codon" cannot be used to refer to an amino acid. Therefore, it is not clear whether applicants are referring to an amino acid sequence of a DNA sequence.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. (See rejection of the phrase "IPNS like SEQ ID NO:1" under 35 U.S.C. 112, 2nd paragraph).

Claim 2 is drawn to a modified *Aspergillus nidulans* comprising a polynucleotide encoding an IPNS like SEQ ID NO:1. Claim 11 is drawn to a polynucleotide encoding an IPNS like SEQ ID NO:1. The claims encompass *A. nidulans* comprising a polynucleotide or a polynucleotide encoding any recombinants, variants and mutants of the IPNS of SEQ ID NO:1, except having an Arg residue at position 212. Therefore, the claims are drawn to a genus of polynucleotides encoding polypeptides having any structure or an *A. nidulans* comprising said genus of polynucleotides. The specification only teaches one species the polynucleotide encoding IPNS of SEQ ID NO:1 and an *A. nidulans* comprising said polynucleotide. One species is not enough and does not constitute a representative number of species to describe the whole genus and there is no evidence on the record of the relationship between the structure of a polynucleotide encoding the IPNS of SEQ ID NO:1 and the structure of polynucleotides encoding any recombinants, variants and mutants of the IPNS of SEQ ID NO:1. Therefore, the specification fails to describe a representative species of the genus comprising polynucleotides encoding any recombinants, variants and mutants of SEQ ID NO:1, except comprising an Arg residue at position 212.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claim 8.

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Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office Action, applicants have requested reconsideration on the amended claims which encompass DNA encoding IPNS like SEQ ID NO:1. Examiner has considered the newly amended claims, as discussed above.

Claims 2 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide encoding an IPNS of SEQ ID NO:1 and an *A. nidulans* comprising said polynucleotide, does not reasonably provide enablement for polynucleotides encoding any recombinants, mutants and variants of SEQ ID NO:1, except having an Arg residue at position 212 or an *A. nidulans* comprising said polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in

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the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claim 2 is drawn to a modified *Aspergillus nidulans* comprising a polynucleotide encoding an IPNS like SEQ ID NO:1. Claim 11 is drawn to a polynucleotide encoding an IPNS like SEQ ID NO:1. The claim encompasses polynucleotides encoding recombinants, variants and mutants of SEQ ID NO:1, except comprising an Arg residue at position 212. or an *A. nidulans* comprising said polynucleotides. Therefore, the claims are drawn to polynucleotides encoding polypeptides having any structure or an *A. nidulans* comprising polynucleotides encoding polypeptides having any structure. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides encoding IPNS variants and mutants, broadly encompassed by the claims. Since the encoded amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the polynucleotide encoding IPNS of SEQ ID NO:1 and an *A. nidulans* comprising said polynucleotide. It would require undue experimentation of the skilled artisan to make and use the claimed variants and mutants of SEQ ID NO:1. In view of the great breadth of the claim, amount of experimentation required to make the

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claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polynucleotides encompassed by the claims.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass polynucleotides encoding all mutants and variants of SEQ ID NO:1, except comprising an Arg residue at position 212, because the specification does not establish: (A) regions of the encoded protein structure which may be modified without affecting IPNS activity; (B) the general tolerance of IPNS to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue in the encoded protein with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

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Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides encoding variants and mutants of SEQ ID NO:1, except comprising an Arg residue at position 212, and an *A. nidulans* comprising said polynucleotides. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotides encoding any mutants and variants of SEQ ID NO:1, except comprising an Arg residue at position 212, having the desired biological characteristics recited in the claim is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

None of the claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652



Manjunath Rao
Primary Patent Examiner 1652